§ 522.2478

- (iii) Limitations. Implant subcutaneously in ear only. Do not use in animals intended for subsequent breeding or in dairy animals. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.
- (3) Pasture cattle (slaughter, stocker, and feeder steers and heifers)—(i) Amount. (A) 40 mg trenbolone acetate and 8 mg estradiol (one implant consisting of 2 pellets, each pellet containing 20 mg trenbolone acetate and 4 mg estradiol) per implant dose.
- (B) 40 mg trenbolone acetate and 8 mg estradiol (one implant consisting of 3 pellets, each of 2 pellets containing 20 mg trenbolone acetate and 4 mg estradiol, and 1 pellet containing 29 mg tylosin tartrate) per implant dose.
- (ii) *Indications for use.* For increased rate of weight gain.
- (iii) Limitations. Implant subcutaneously in ear only. Do not use in animals intended for subsequent breeding or in dairy animals. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

[60 FR 4376, Jan. 23, 1995, as amended at 61 FR 29480, June 11, 1996; 61 FR 41499, Aug. 9, 1996; 62 FR 28629, May 27, 1997; 64 FR 42597, Aug. 5, 1999; 64 FR 48294, Sept. 3, 1999; 65 FR 10706, Feb. 29, 2000; 65 FR 26748, May 9, 2000; 65 FR 45879, July 26, 2000; 65 FR 70663, Nov. 27, 2000; 66 FR 47961, Sept. 17, 2001; 67 FR 5724, Feb. 7, 2002; 67 FR 78358, Dec. 24, 2002; 68 FR 42250, July 17, 2003; 68 FR 48785, Aug. 15, 2003; 68 FR 55200, 55201, Sept. 23, 2003; 69 FR 500, Jan. 6, 2004; 69 FR 7116, Feb. 13, 2004; 69 FR 12271, Mar. 16, 2004; 69 FR 13735, Mar. 24, 2004; 69 FR 68253, Nov. 24, 2004; 70 FR 8290, Feb. 18, 2005]

§ 522.2478 Trenbolone acetate and estradiol benzoate.

- (a) *Specifications*. Each implant dose consists of:
- (1) 8 pellets, each pellet containing 25 milligrams (mg) trenbolone acetate and 3.5 mg estradiol benzoate.
- (2) 4 pellets, each pellet containing 25 mg trenbolone acetate and 3.5 mg estradiol benzoate.

- (b) Sponsor. See No. 000856 in $\S510.600$ (c) of this chapter.
- (c) Related tolerances. See §§ 556.240 and 556.739 of this chapter.
- (d) Conditions of use—(1) Steers fed in confinement for slaughter. (i) For an implant as described in paragraph (a)(1) of this section:
- (A) *Amount.* 200 mg trenbolone acetate and 28 mg estradiol benzoate.
- (B) *Indications for use.* For increased rate of weight gain and improved feed efficiency.
- (C) Limitations. Implant subcutaneously in ear only. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.
- (ii) For an implant as described in paragraph (a)(2) of this section:
- (A) *Amount*. 100 mg trenbolone acetate and 14 mg estradiol benzoate.
- (B) *Indications for use.* For increased rate of weight gain.
- (C) Limitations. Implant subcutaneously in ear only. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.
- (2) Heifers fed in confinement for slaughter—(i) Amount. 200 mg trenbolone acetate and 28 mg estradiol benzoate (as described in paragraph (a)(1) of this section).
- (ii) *Indications for use*. For increased rate of weight gain.
- (iii) Limitations. Implant subcutaneously in ear only. Not for subsequent breeding dairy or beef replacement heifers. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

[67 FR 78972, Dec. 27, 2002, as amended at 69 FR 67818, Nov. 22, 2004]

$\$\,522.2483$ Sterile triamcinolone acetonide suspension.

- (a) *Specifications.* Each milliliter of suspension contains 2 or 6 milligrams triamcinolone acetonide.
- (b) Sponsor. See 000010 and 053501 in \$510.600(c) of this chapter.

Food and Drug Administration, HHS

- (c) Conditions of use—(1) Amount—(i) Dogs and cats—(a) Intramuscular or subcutaneous. Single injection of 0.05 to 0.1 milligram (mg.) per pound of body weight in inflammatory, arthritic, or allergic disorders. Single injection of 0.1 mg. per pound of body weight in dermatologic disorders. If symptoms recur, the dose may be repeated, or oral corticosteroid therapy may be instituted. ¹
- (b) Intralesional. 1.2 to 1.8 mg., divided in several injections, spaced around the lesion at 0.5 to 2.5 centimeters apart depending on the size. At any one site the dose injected should not exceed 0.6 mg. and should be well into the cutis to prevent rupture of the epidermis. When treating animals with multiple lesions, do not exceed a total dose of 6 mg.
- (c) Intra-articular and intrasynovial. Single injection of 1 to 3 mg. dose, dependent on size of joint and severity of symptoms. After 3 or 4 days, repeat dosage if indicated. If initial results are inadequate or too transient, dosage may be increased, not to exceed 3 mg.
- (ii) Horses—(a) Intramuscular or subcutaneous. Single injection of 0.01 to 0.02 mg. per pound of body weight. Usual dose, 12 to 20 mg.
- (b) Intra-articular and intrasynovial. Single injection of 6 to 18 mg. dose, dependent on size of joint and severity of symptoms. After 3 or 4 days, repeat dosage if indicated. If initial results are inadequate or too transient, dosage may be increased, not to exceed 18 mg.
- (2) Indications for use. Treatment of inflamation and related disorders in dogs, cats, and horses; 1 and management and treatment of acute arthritis and allergic and dermatologic disorders in dogs and cats.
- (3) *Limitations.* (i) Do not use in viral infections. With bacterial infections, appropriate antibacterial therapy should be used.
- (ii) Do not use in animals with tuberculosis, chronic nephritis, or cushingoid syndrome, except for emergency therapy.
- ¹These conditions are NAS/NRC reviewed and are deemed effective. Applications for these uses need not include the effectiveness data specified by §514.111 of this chapter, but may require bioequivalency and safety information.

- (iii) Not for use in horses intended for food
- (iv) Clinical and experimental data have demonstrated that corticosteroids administered orally or parenterally to animals may induce the first stage of parturition when administered during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.
- (v) Do not use in the treatment of laminitis.
- (vi) Intra-articular injection in equine leg injuries may produce osseous metaplasia.
- (vii) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[43 FR 4976, Feb. 7, 1978, as amended at 50 FR 41490, Oct. 11, 1985; 52 FR 1903, Jan. 16, 1987; 53 FR 40728, Oct. 18, 1988; 62 FR 35077, June 30, 1997]

§ 522.2582 Triflupromazine hydrochloride injection.

- (a) Specifications. Triflupromazine hydrochloride injection contains 20 milligrams of triflupromazine hydrochloride in each milliliter of sterile aqueous solution.
- (b) *Sponsor.* See No. 053501 in §510.600(c) of this chapter.
- (c) Conditions of use. (1) The drug is used in dogs, cats, and horses to relieve anxiety and to help control psychomotor overactivity as well as to increase the tolerance of animals to pain and pruritus. The drug is indicated in various office and clinical procedures which require the aid of a tranquilizer, antiemetic, or preanesthetic.¹
- (2) The drug is administered to dogs either intravenously at a dosage level of 0.5 to 1 milligram per pound of body weight daily, or intramuscularly at a dosage level of 1 to 2 milligrams per pound of body weight daily. It is administered to cats intramuscularly at a dosage level of 2 to 4 milligrams per pound of body weight daily. It is administered to horses intravenously or intramuscularly at a dosage level of 10 to 15 milligrams per 100 pounds of body